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INTELLECTUAL PROPERTY LAW

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THOMAS K. PLUNKETT**
GUANYAO CHENG***

PATENT AGENTS
DAVID T. XUE, PH.D.

*MASSACHUSETTS, NEW YORK
**VIRGINIA
***ILLINOIS

RECEIVED

21 SEP 2006

Legal Staff
International Division

D. BENJAMIN BORSON, PH.D.
dbb@foml.com

21 September 2006

BY FACSIMILE ONLY (571.273.0459) - 16 pages total

PCT Legal Office
USPTO International Division
Mail Stop PCT
P. O. Box 1450
Alexandria, VA 22313

Re: U.S. Patent Application No.: 10/568,573
(Which is a 371 (c) to PCT Application No. PCT/US2004/027187 filed 19 August 2004)
Entitled: SOMATOGENIC THERAPY USING A 20KDA PLACENTAL VARIANT OF GROWTH HORMONE
Inventors: Peter David Gluckman, *et al.*
Attorney Docket No.: ERNZ-01082US3

Dear Sir/Madam:

This letter is in regard to the above-referenced United States national phase patent application.

Applicants believe that \$150.00 was erroneously credited to our deposit account for the Search Fee. Please see our comments below:

- 1) On 16 February 2006, a Transmittal Letter to the United States Designated/Elected Office Concerning A Filing Under 35 U.S.C. 371 (PTO-1390) was submitted via Express Mail.

Since the International Search Report was prepared by the European Patent Office, Applicants paid \$200.00 (Applicant claimed small entity status) for the Search Fee.

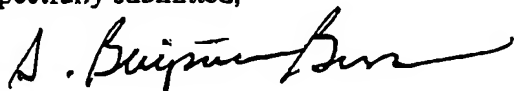
- 2) On 13 July 2006, our USPTO Deposit Account was credited \$150.00.
- 3) After numerous attempts to contact Examiner Patricia Booker regarding this credit, we received a voice mail from her in which she stated that the credit was issued because the United States was the Searching Authority.

Attached please find a copy of PTO Form 1390, and the International Search Report and Written Opinion of the International Searching Authority, issued by the European Patent Office on 24 February 2005.

In light of the above information, Applicants respectfully request that \$150.00 be debited from our deposit account No. 06-1325.

Thank you for your attention to this matter. Please feel free to contact us with any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D. Benjamin Borson". The signature is fluid and cursive, with a long horizontal stroke at the end.

D. Benjamin Borson, Ph.D.
USPTO Reg. No.: 42,349

DBB/nan
Attachments
frdp/emz/1082us3.001.wpd

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER ERN2-016US3 U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Unassigned
INTERNATIONAL APPLICATION NO. PCT/US2004/027187	INTERNATIONAL FILING DATE 19 August 2004	PRIORITY DATE CLAIMED 20 August 2003
TITLE OF INVENTION SOMATOGENIC THERAPY USING A 20KDA PLACENTAL VARIANT OF GROWTH HORMONE		
APPLICANT(S) FOR DO/EO/US GLUCKMAN, Peter; GILMOUR, Stewart; VICKERS, Mark, Hedley; BREIER, Bernhard		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input checked="" type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11 to 20 below concern document(s) or information included:</p> <ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4). 		

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) Unassigned	INTERNATIONAL APPLICATION NO. PCT/US2004/027187	ATTORNEY'S DOCKET NUMBER ERNZ-01016US3
20. Other items or Information: Express Mail Label No.: EV 385 256 912 US mailed 16 February 2006; Copy of the International Search Report and Written Opinion of the International Searching Authority (EP); PCT Forms – PCT/IB/304 and PCT/IB/308 (two sheets); and Return Receipt Postcard		
The following fees have been submitted		CALCULATIONS PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300		\$ 300.00
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200		\$200.00
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500		\$ 400.00
TOTAL OF 21, 22 and 23 =		\$ 900.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)
- 100 =	/50 =	x \$250
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	21 - 20 =	1
Independent claims	6 - 3 =	3
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ \$360
TOTAL OF ABOVE CALCULATIONS =		\$ 1,550.00
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$ 775.00
SUBTOTAL =		\$ 775.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$
TOTAL NATIONAL FEE =		\$ 775.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		\$
TOTAL FEES ENCLOSED =		\$ 775.00
		Amount to be refunded:
		\$
		Amount to be charged:
		\$

- a. ☒ A check in the amount of \$ 775.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. 06-1325 in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to
Deposit Account No. 06-1325. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information
should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must
be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

D. Benjamin Borson, Ph.D.
Filester Meyer LLP
Four Embarcadero Center, 4th Floor
San Francisco, CA 94111-4156

D. Benjamin Borson
SIGNATURE

D. Benjamin Borson, Ph.D.
NAME

42,349
REGISTRATION NUMBER

PATENT COOPERATION TREATY

RECEIVED

MAR 01 2005

From the INTERNATIONAL SEARCHING AUTHORITY

PCT FLIESLER MEYER LLP

To:

FLIESLER MEYER LLP
Attn. Borson, D. Benjamin
Four Embarcadero Center, 4th Floor
San Francisco CA 94111-4156
UNITED STATES OF AMERICA

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference ERNZ01016W00 ✓	Date of mailing (day/month/year) 24/02/2005
International application No. PCT/US2004/027187 ✓	International filing date (day/month/year) 19/08/2004 ✓
Applicant NEUREN PHARMACEUTICALS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders


Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Sandrine Polenzani
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INTERNATIONAL COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ERNZ01016W00	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No. PCT/US2004/027187	International filing date (day/month/year) 19/08/2004	(Earliest) Priority Date (day/month/year) 20/08/2003
Applicant NEUREN PHARMACEUTICALS, INC.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 05 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☒ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box II).

3. ☐ Unity of invention is lacking (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2004/027187

Box No. 1 Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☒ furnished subsequently to this Authority for the purpose of search
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

Int'l Patent Application No
PCT/US2004/027187A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K38/27 A61P19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/101002 A (GENODYSSEE; ESCARY, JEAN-LOUIS) 19 December 2002 (2002-12-19) page 14, lines 25-28; claims 41,40,26; sequence 13	1-21
X	US 6 399 565 B1 (ASADA NORIAKI ET AL) 4 June 2002 (2002-06-04) cited in the application column 4, lines 30-43; claim 1 column 2, lines 54-60	1-21
Y	US 6 417 237 B1 (DADEY ERIC J ET AL) 9 July 2002 (2002-07-09) column 6, lines 19-40,58 abstract	1-21

-/-

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

8 February 2005

Date of mailing of the international search report

24/02/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Ludwig, G

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/027187

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 916 345 A (SUMITOMO PHARMACEUTICALS COMPANY, LIMITED) 19 May 1999 (1999-05-19) claim 1 abstract	1-21
A	----- BOGUSZEWSKI C L ET AL: "Cloning of two novel growth hormone transcripts expressed in human placenta" JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, NEW YORK, NY, US, vol. 83, no. 8, August 1998 (1998-08), pages 2878-2885, XP002284559 ISSN: 0021-972X abstract	
A	----- EP 0 587 427 A (MITSUI TOATSU CHEMICALS, INC) 16 March 1994 (1994-03-16) pages 12-13 abstract -----	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/027187

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 02101002	A	19-12-2002	EP 1295938 A1 WO 02101002 A2	26-03-2003 19-12-2002
US 6399565	B1	04-06-2002	CN 1145808 A EP 0753307 A2 JP 9216832 A NZ 286884 A AU 680792 B2 AU 5625596 A	26-03-1997 15-01-1997 19-08-1997 19-12-1997 07-08-1997 16-01-1997
US 6417237	B1	09-07-2002	AU 6327701 A BR 0111506 A CA 2409268 A1 CN 1441666 T EP 1286659 A2 JP 2003535149 T WO 0193911 A2 ZA 200209229 A	17-12-2001 24-06-2003 13-12-2001 10-09-2003 05-03-2003 25-11-2003 13-12-2001 07-08-2003
EP 0916345	A	19-05-1999	AU 3357997 A EP 0916345 A1 US 6225283 B1 CA 2260148 A1 WO 9801152 A1	02-02-1998 19-05-1999 01-05-2001 15-01-1998 15-01-1998
EP 0587427	A	16-03-1994	DE 69318909 D1 DE 69318909 T2 EP 0587427 A1 JP 3398427 B2 JP 6269292 A US 5496713 A	09-07-1998 24-12-1998 16-03-1994 21-04-2003 27-09-1994 05-03-1996

INTERNET COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/027187

International filing date (day/month/year)
19.08.2004

Priority date (day/month/year)
20.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K38/27, A61P19/00

Applicant
NEUREN PHARMACEUTICALS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Ludwig, G

Telephone No. +49 89 2399-8698



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/027187

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☒ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/027187

Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21 (cf.text)
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/027187

- D1: WO 02/101002 A (GENODYSSEE; ESCARY, JEAN-LOUIS) 19 December 2002 (2002-12-19)
- D2: US-B1-6 399 565 (ASADA NORIAKI ET AL) 4 June 2002 (2002-06-04)
- D3: US-B1-6 417 237 (DADEY ERIC J ET AL) 9 July 2002 (2002-07-09)
- D4: EP-A-0 916 345 (SUMITOMO PHARMACEUTICALS COMPANY, LIMITED) 19 May 1999 (1999-05-19)
- D5: BOGUSZEWSKI C L ET AL: "Cloning of two novel growth hormone transcripts expressed in human placenta" JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, NEW YORK, NY, US, vol. 83, no. 8, August 1998 (1998-08), pages 2878-2885, XP002284559 ISSN: 0021-972X
- D6: EP-A-0 587 427 (MITSUI TOATSU CHEMICALS, INC) 16 March 1994 (1994-03-16)

Item V:

1. D1 discloses the use of a 20kDa hGH-V (human growth hormone variant) polypeptide which is identical to peptide no.7 as used in the application for the treatment of growth hormone deficiency and of diseases/disorders associated with it. e.g. insulin resistance and retinopathy.

D2 discloses discloses the use of 20kDa hGH-V (human growth hormone variant) polypeptides whose sequence is closely related to peptide no.7 as used in the application for the treatment of growth hormone deficiency and of diseases/disorders associated with it. The protein is said to have only a weak activity in inducing glucose intolerance.

D3 discloses the use of hGH for the treatment of osteoporosis, kidney disease, hypertension and depression.

D4 discloses the use of hGH for the treatment of anorexia.

Documents D5 and D6 disclose the cloning and production, respectively, of the

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/027187

20 kDa hGH-V protein.

2. Claim 1 is not novel vis-a-vis documents D1 or D2.
Claims 2-21 are not inventive in view of these documents (cf. also documents D3-D4 which relate to diseases/disorders treatable by hGH).
3. For the assessment of the present claims 1-21 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.